NC SYSTEMS, INC.

SERVICES FOR NUCLEAR IMAGING

MAR 4 2002

510(K) SUMMARY

SUBMITTER IDENTIFICATION

Applicant's Name and Street Address: Nuclear Cardiology Systems, Inc.
dba NC Systems, Inc.
5660 Airport Blvd., Suite 101
Boulder, Colorado 80301

Contact Person: Charles H. Rose

Telephone and Fax Numbers of Contact Person: T-(303) 541-0044
800-548-4024
F-(303) 541-0066

Address of Manufacturing Site: Alsotorokvesz 14
H-1022 Budapest, Hungary

Date of Submission: October 10, 2001

DEVICE NAME

Device Name (common): Gamma Camera
Proprietary Name: NeuroSpect QUAD Gamma Camera
Classification Name: Emission Computed Tomography System

INTRODUCTION

This 510(k) Premarket Notification has been prepared to demonstrate that the NeuroSpect QUAD Gamma Camera, manufactured by NC Systems, Inc., is substantially equivalent to the Picker Prism 3000 which has previously underwent the 510(k) premarket notification process. The NeuroSpect QUAD nuclear imaging system had four (4) rectangular field of view detector heads.

INTENDED USE

The intended use of the NeuroSpect QUAD Gamma Camera is to detect the location and distribution of gamma ray emitting radionuclides in the brain and store the data for analysis. This device includes accessories such as signal analysis and display equipment previously approved, K010726, patient and equipment supports, component parts and accessories.

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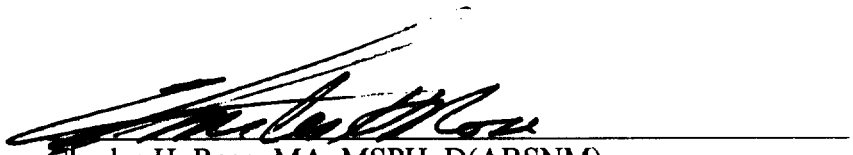
DETERMINE OF SUBSTANTIAL EQUIVALENCE

The intended use of the two devices is identical. The system does not include data analysis capability. The data is stored and available for transmission to, or retrieval by, existing commercially available data analysis software and accompanying equipment.

The NeuroSpect QUAD has been deemed safe and effective and is certified to the same electrical safety standards as the predicate device by a third party organization prior to use on patients. a matrix was constructed comparing the features and intended use of the NeuroSpect QUAD with the predicate device. We conclude that the NeuroSpect QUAD is substantially equivalent to the predicate device and that no new safety or effectiveness concerns are raised.

I certify that, in my capacity as the CEO of NC Systems, Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety identifiers, and trade secret and confidential commercial information, as defined in 21CFR20.61



Charles H. Rose, MA, MSPH, D(ABSNM)
30 November 2001

510(k) #K013353

NATIONAL HEADQUARTERS AND LABORATORIES
5660 AIRPORT BLVD., SUITE 101
BOULDER, COLORADO 80301

TOLL FREE: 800-548-402
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

Mr. Charles H. Rose
CEO
Nuclear Cardiology Systems, Inc.
5660 Airport Blvd., Suite 101
BOULDER CO 80301

Re: K013353
Trade/Device Name: NeuroSpect QUAD Gamma Camera
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: November 30, 2001
Received: December 4, 2001

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): 013353

Device Name: NeuroSpect QUAD Gamma Camera

Indications For Use:

NeuroSpect QUAD is intended to detect and obtain planar and SPECT images of the distribution of a gamma emitting radionuclide in the brain and store the data, when the radionuclide is administered in the body.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013353

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)